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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,614	12/08/1999	Timothy Peter Bonnert	T1481	1165

7590

08/23/2002

Patent Department
Merck & Co Inc
P.O. Box 2000
Rahway, NJ 07065-0907

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 08/23/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/445,614

Applicant(s)

BONNERT, TIMOTHY PETER

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12,13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 6,10,12,13,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth in Paper 18, 6/11/02, have been entered in full.

Claims 1-3, 5-10, 12, 13, 15, 16 are pending.

Claims 6, 10, 12, 13, 15, 16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as set forth previously (Paper 12, 12/8/01).

Priority

Acknowledgment is again made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 12/8/1998. Applicant asserts that a certified copy of this application was included in Applicant's response of Paper 18, however no copy can be found. Applicant is invited to submit another certified copy of the foreign application to obtain priority as required by 35 U.S.C. 119(b).

Sequence Rules Compliance:

Applicant is notified that the application now appears to be in compliance with the requirements of 37 CFR 1.821-1.825.

Withdrawn rejections:

The rejection of claim 1 under 35 U.S.C. 101, as set forth previously, is withdrawn. Applicant correctly points out that the claim had previously been amended to obviate the rejection.

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The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as set forth previously, is withdrawn in view of Applicant's amendments.

The rejections Claim 3 under 35 U.S.C. 112, first paragraph, as set forth previously, is withdrawn in view of Applicant's amendments.

The rejection of claims 3 and 5 under 35 U.S.C. 102(e) as being anticipated by US Patent 5834183, as set forth previously, is withdrawn in view of Applicant's amendments.

The rejection of claim 3 under 35 U.S.C. 102(b) as being anticipated by the SIGMA Product Catalogue, 1992, as set forth previously, is withdrawn in view of Applicant's amendments.

Maintained rejections:

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendment to claim 5 does not obviate the rejections set forth previously. There is no qualification of the term "probe" in the claim. The specification does not set forth any degree of specificity that a "probe" must have – such specificity defines the metes and bounds of the claim Applicant is seeking protection for. The skilled artisan can not know if a given polynucleotide having, in part, a sequence of SEQ ID NO: 4-19 is encompassed by the claim. One way to obviate this rejection would be to incorporate specific hybridization conditions into the claim, however it does not appear that the specification contemplates any specific set of hybridization conditions

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Claim 5 stands rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office Action (pages 5-6 of Paper 12) and for the following reason addressing the amendment to the claim. Even though the claim now recites SEQ ID NO: 4-19, the term “comprising” allows the probe to have little structural resemblance to SEQ ID NO: 1. Thus, the specification, while being enabling for polynucleotide probes comprising an oligomer of SEQ ID NO: 4-19, wherein said probe does not differ in sequence from a polynucleotide encoding a polypeptide of SEQ ID NO: 2 or fragment of said polynucleotide, does not reasonably provide enablement for polynucleotides comprising an oligomer of SEQ ID NO: 4-19, wherein said probe differs in sequence from a polynucleotide encoding a polypeptide of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass any and all polynucleotides that contain either of SEQ ID NO: 4-19, and can be termed a “probe”. As set forth above, the term “probe” does not provide a meaningful limitation. Further, the size of SEQ ID NO: 4-19 is small, comprising less than 1% of the sequence of SEQ ID NO: 1, thus the claims encompass a practically limitless number of polynucleotides that could be as little as 1% identical to a polynucleotide encoding a polypeptide SEQ ID NO: 2. As set forth previously, the specification does not provide sufficient guidance to make and use the invention of such scope.

Applicant’s argument, that the amendment to the claim has obviated the rejection, is not persuasive for the reasons of record and as discussed above.

Claim 5 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses polynucleotides of SEQ ID NO: 4-19 which are derived from the sequence of SEQ ID NO: 1, yet as discussed above and previously, the claims recite “comprising” and thus encompass a vast genus of polynucleotides not described in the specification, e.g., sequences from other species, mutated sequences, allelic variants, or sequences that have a recited degree of identity. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph, as set forth previously.

With the exception of the of the polynucleotide of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants, as set forth previously. Therefore, only polynucleotide probes comprising an oligomer of SEQ ID NO: 4-19, wherein said probe does not differ in sequence from a polynucleotide encoding a polypeptide of SEQ ID NO: 2, and a heterologous sequence (e.g. vector), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claims 1, 3, 5, 7, 8, 9 stand rejected under 35 U.S.C. 102(a) as being anticipated by Caterina et al. Nature 398(436-441), April 20, 1999. Caterina et al. disclose polynucleotides comprising the coding region of the polynucleotide of SEQ ID NO: 1 (see attached sequence alignment), probes specific to said polynucleotide, e.g. the full length polynucleotide would be expected to comprise SEQ ID NO: 4-19, vectors, host cells, and methods of making a polypeptide (see Methods). The rejection is maintained because the requirements for obtaining

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priority under 35 U.S.C. 119(b) have, apparently, not been met. The required certified copy does not appear in the application even though Applicant's response indicated one should be enclosed.

New Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 5, 7, 8, 9 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6335180, filed 1/22/1999.

US Patent No. 6335180 disclose a polynucleotide (SEQ ID NO: 35) comprising the coding region of the polynucleotide of SEQ ID NO: 1 (see attached sequence alignment), encoding a polypeptide that is 100% identical to SEQ ID NO: 2, probes specific to said polynucleotide (e.g. col 13-15), e.g. full length SEQ ID NO: 35 would be expected to comprise SEQ ID NO: 4-19, vectors, host cells, and methods of making a polypeptide (e.g. col 16).

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Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

WJ
8/21/02


CLAIRE KAUFMAN
PATENT EXAMINER

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Sequence alignment: US Patent No. 6335180- SEQ ID NO: 35 with 09445614-1

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RESULT 1
US-09-235-451-35
; Sequence 35, Application US/09235451
; GENERAL INFORMATION:
; APPLICANT: Julius, David J.
; APPLICANT: Caterina, Michael J.
; APPLICANT: Brake, Anthony J.
; TITLE OF INVENTION: NUCLEIC ACID SEQUENCES ENCODING
; TITLE OF INVENTION: CAPSAICIN RECEPTOR AND CAPSAICIN RECEPTOR-RELATED
; TITLE OF INVENTION: POLYPEPTIDES AND USES THEREOF
; FILE REFERENCE: 9076/084CIP
; CURRENT APPLICATION NUMBER: US/09/235,451
; CURRENT FILING DATE: 1999-01-22
; PRIOR APPLICATION NUMBER: 60/072,151
; PRIOR FILING DATE: 1998-01-22
; PRIOR APPLICATION NUMBER: 08/915,461
; PRIOR FILING DATE: 1997-08-20
; NUMBER OF SEQ ID NOS: 48
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 35
; LENGTH: 2380
; TYPE: DNA
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: CDS
; LOCATION: (19)...(2313)
; OTHER INFORMATION: Human VR2
US-09-235-451-35
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Best Local Similarity 100.0%; Pred. No. 0;
Matches 2379; Conservative 0; Mismatches 1; Indels 0; Gaps 0;
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